

SPL R4 Training - Preparing OTC Drug Product Electronic Drug Listing Submissions

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OTC Content of Labeling

- Drug Facts information is the content of labeling
- Place Drug Facts content in “body” of SPL document.

OTC SPL Documents

- Amount of products per SPL
 - one (preferred)
 - many similar products with the same active ingredient

Marketing Category

- Use appropriate marketing category
 - OTC monograph final
 - OTC monograph not final

Regulatory Citation/Application

- Use appropriate regulatory citation
- See SPL web page for list of acceptable citations to be used in your SPL document.
- Enter citation number as: “part_____”
- Enter application number as “NDA_____”(six digits for application numbers)

eDRLS E-mail Address

- Validator Lite link:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- eDRLS e-mail address: edrls@fda.hhs.gov
- DailyMed website:
<http://dailymed.nlm.nih.gov/dailymed/about.cfm>

Sample System Generated Validation Report

Validation Report

Document b57873cf-1ad4-4f30-bdb6-4f99baf5e46b (version 1) validated on 200-05-20 at 14:35 contained 2 errors.

Overview of Errors

1. [Value of version number must be greater than the value of any previously submitted version for the same setId](#)
2. [id must be unique across all documents](#)

XML View

Click on the XML tag to expand or collapse. The marks identified like this **2** indicate thus many errors are in the collapsed element. Errors are shown in **red comments, such as this**. Double-click to expand all.

```
<document xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd" v:schemaVersion="2.0">
  <!-- Value of version number must be greater than the value of any previously submitted version for the same setId [1.3.16, go back] -->
  <id root="b57873cf-1ad4-4f30-bdb6-4f99baf5e46b">
    <!-- id must be unique across all documents [1.3.5, go back] -->
    </id>
    <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
    <effectiveTime value="20090520"/>
    <setId root="a41f2c3e-3b09-49d4-8aaf-3537ce86b757"/>
    <versionNumber value="1"/>
    <author ... >
    <component ... >
  </document>
```

Common Errors

- Uploading only XML file (Upload folder containing SPL (XML) file)
- Spaces preceding or following e-mail or telephone number
- Inclusion of “Thumbs.db” file
- Zipping files
- Sending listing or registration file to Gateway “center” other than “OC”
- Mismatched DUNS Numbers

Test Your SPL R4 Docs

- Provision of SPL R4 Validator Tool
- Test SPL R4 files prior to submission
- Discover ~90 – 95% of validation errors prior to submission.
- Schematron technology – permits quick updates to validation procedures
- FDA in collaboration with Pragmatic Data made available a validation tool:
[Pragmatic Validator Lite™](#)

Use These Documents

- **Use** these most recent version of these source documents when authoring your SPL:
 - FDA SPL schema
 - FDA SPL stylesheet
 - SPL Implementation Guide
 - SPL Validation Procedures
 - SPL XForms instructions document
 - Appropriate regulatory guidance documents
 - Appropriate labeling and listing regulations

*** Most SPL-related regulatory guidance and technical documents are available on FDA Data Standards Council website – SPL Labeling Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

QUESTIONS